

REMARKS

Claims 1-41 are now pending in the application. Claims 24-39 have been withdrawn from consideration. Claims 1, 8, 10-11, 16, and 22-23 have been amended. Support for the claim amendments is found throughout Applicants' specification and at Page 3, lines 7-8; Page 4 lines 1-12; and Page 9, lines 26-31, for example. Claim 10 has been amended to address a mere informality and is of equivalent scope as originally filed. Applicants have amended Claims 1, 11, and 16 to accord with the election (designated as Group V) in response to the restriction requirement. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

REJECTION UNDER DOUBLE PATENTING

Applicants note that Claims 1-10, 20 and 21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 and 20 of co-pending U.S. Application Serial No. 10/480,019. U.S. Application Serial No. 10/480,019 is still pending and Applicants reserve the right to respond to this rejection at the appropriate time, if the rejection should become non-provisional.


REJECTION UNDER 35 U.S.C. § 112

Claims 1-9, 18, 20, 22 and 40 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed. Applicants have amended Claim 1 to remove the rejected R'

moieties $-(O)_a-(CH_2)_b-(O)_a-R$ and $-(O)_a-(CH_2)_b$ -5- or 6-membered aromatic heterocycle containing from 1 to 4 heteroatoms selected from nitrogen, oxygen and sulfur, by removing this specific language. Additionally, Applicants have now included R' moieties of $-O-(CH_2)_2-O-CH_3$, $-O-CH_2-(2,2\text{-dimethyl-1,3-dioxolan-4-yl})$, and $-CO-NH$ phenyl, support for which is found in Applicants' specification at Page 4 lines 1-12; and Page 9, lines 26-31, for example.

Claims 1-9, 11-18, 20-23, 40 and 41 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse these rejections. Specifically, Applicants have addressed the following:

(a) Claims 1-5, 7-9, 18, 20, 22 and 40 stand rejected for indefiniteness because it is not known what is meant by the moiety " $HC(=NR_6)(NHR_7)$ " in the definition

of R_1 . Applicants have amended Claim 1 to recite the moiety  and believe that the rejection is now moot. Claims 1-5, 7-9, 18, 20, 22 and 40 should now be allowable.

(b) Claims 1-7, 9, 18, 20, 22 and 40 stand rejected for indefiniteness because of the moiety " CH_2SO_3H " in the definition of Y. Applicants have amended Claim 1 to recite CH_2SO_3H , where the 3 is subscripted. Applicants believe this amendment should overcome the rejection and that Claim 1 and Claims 2-6, 9, 18, 20, 22, and 40, which depend upon Claim 1 are allowable.

(c)-(d) Claim 8 has been amended to recite R_8 is selected from OY and OY_1 , where OY or OY_1 are respectively selected from the appropriate Markush grouping of moieties. Applicants respectfully submit that amended Claim 8 is now in the proper format and that the rejection be withdrawn. Further, Claim 8 has also been amended to

replace the moiety "OY1" with the moiety "OY₁." Applicants believe that these amendments should render the rejections of Claim 8 moot.

(e)-(h) In Claim 11, the "and" following the definition of R'₁ has been removed. Claim 11 has also been amended to remove the recitation of "the nucleus" prior to the aryl or aralkyl in the definition of R₉. The (CH₂)_{n₁}R'₅ of R'₄ has been amended to provide antecedent basis for the variable n'₁. Applicants believe that these amendments to Claim 11 render the rejections moot.

(i)-(j) Claims 22 and 23 have been amended to more particularly point out and distinctly claim the invention. Claim 22 now recites a pharmaceutical composition containing an active ingredient comprising a compound as defined in claim 1 that is a β -lactamase inhibiting agent, wherein the active ingredient further comprises a β -lactam medicament. Thus, Claim 22 provides a compound of Claim 1 that is a β -lactamase inhibiting agent as a part of an active ingredient in a pharmaceutical composition. The active ingredient of the pharmaceutical composition further includes a β -lactam inhibiting agent. Similarly, Claim 23 has been amended to recite a pharmaceutical composition containing an active ingredient a compound as defined in claim 10 that is a β -lactamase inhibiting agent, where the active ingredient further comprises a β -lactam medicament. Applicants respectfully submit that these amendments clarify the claimed invention and request reconsideration of these claims.

(k)-(l) Claims 22, 23, 40 and 41 stand rejected for allegedly being vague and indefinite regarding what is meant by " β -lactamase inhibiting agent" and " β -lactam medicament agent." In rejecting a claim under 112, Second Paragraph, it is incumbent upon the Examiner to establish that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claim when read in light of

the supporting specification. *Ex parte Cordova*, 10 USPQ.2d 1949, 1952 (BPAI 1987). “[T]he definiteness of the [claim] language employed must be analyzed-not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *In re Moore*, 169 USPQ 236, 238 (CCPA 1971).

Applicants respectfully submit that one of skill in the art appreciates that a “ β -lactamase inhibiting agent” is a compound that exhibits β -lactamase inhibiting activity. Similarly, a “ β -lactam medicament agent” is one that prevents bacterial growth via β -lactam-type compounds, which are well-known antibiotics. When bacteria generate β -lactamase, they become resistant to the β -lactam-type antibiotics. The β -lactamase inhibiting activity prevents the bacteria from producing substances (e.g., β -lactamase) that would otherwise provide resistance to such antibiotics. In other words, β -lactamase inhibiting compounds inhibit the natural defenses of bacteria. See for example, Applicants’ specification at Page 23, lines 18-30, for example, which describes various aspects associated with the β -lactamase inhibiting activity. These claim terms are not indefinite, because one having skill in the art can appreciate the meaning of these terms, particularly in view of the specification. The Examiner has not established a *prima facie* case of indefiniteness, because the Examiner has not demonstrated how the claim language would be indefinite to one of skill in the art and reconsideration and allowance of Claims 22, 23, 40, and 41 is requested. Applicants respectfully submit that the amendments made to Claims 1, 8, 10, 11, 16, 22, and 23 should bring Claims 1-18, 20-24 and 39-41 into condition for allowance.

ALLOWABLE SUBJECT MATTER

The Examiner states that Claim 19 would be allowable if rewritten in independent form. Applicants thank the Examiner for the indication of allowable subject matter. Applicants respectfully submit that all of Claims 1-23 and 40-41 are in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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